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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,886	11/18/2005	Jurgen Dorn	1016710007P	4465

34284 7590 10/29/2008

Rutan & Tucker, LLP.
611 ANTON BLVD
SUITE 1400
COSTA MESA, CA 92626

EXAMINER	
BLATT, ERIC D	

ART UNIT	PAPER NUMBER
3734	

MAIL DATE	DELIVERY MODE
10/29/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/552,886	DORN, JURGEN	
	Examiner	Art Unit	
	Eric Blatt	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7-1-2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-19 and 21-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sullivan et al. (US 6,607,551).

Regarding claims 1, 3, 5, 10, 11, 19, 28, Sullivan discloses a delivery system and a method of loading a self-expanding stent into a delivery sheath. Said system and method include providing a self-expanding stent graft 34 (Column 1, Lines 18-27) comprising a stent matrix and graft layers of covering lining the inside and outside of said stent matrix. (Column 1, Lines 18-27) Although Sullivan does not explicitly state that the inner and outer layers of graft material are bonded to one-another, it would have been obvious to one of ordinary skill in the art to have the inner and outer layers of graft material be bonded to one-another in order to hold the stent graft together as a single entity. The stent matrix has apertures. (Figure 2B) It would have been obvious for said bonding between the luminal and abluminal coverings to occur across the stent matrix through said apertures since the covering layers may contact one another through said apertures. There is a stent pusher 30A (Figure 3A) that has radially outwardly extending protrusions 38 distributed along the length of the stent graft 34.

Said stent pusher 30A is also considered an inner catheter 30A. The stent graft 34 is compressed into a delivery configuration onto the stent pusher 30A such that the protrusions 38 engage the inner surface of the stent graft 34. (Column 3, Lines 19-51)

Sullivan does not speak directly to the issue of compressing the stent radially inwardly such that the protrusions deform the covering material but do not reach radially outwardly as far as the luminal envelope. The disclosure of Sullivan is primarily concerned with an embodiment wherein the stent is uncovered. Sullivan does, however, teach that the retention means disclosed therein is compatible with a covered stent, and further teaches that the protrusions may merely be in frictional engagement with the inner periphery of the stent. (Column 6, Lines 3-4) By compressing the stent graft 34 onto the protrusions 38, the protrusions 38 inherently deform the covering material. It would have been obvious to one of ordinary skill in the art at the time of the invention to compress the stent such that the protrusions do not extend outwardly through the covering layer into the luminal envelope in order to prevent damage to the stent since Sullivan teaches that frictional engagement alone is sufficient to retain the stent.

Sullivan discloses that an endwise force is imposed on the stent pusher 30A so that the covering material transfers the pushing force from the protrusions 38 of the stent pusher 30A to the stent matrix to advance the stent 34 into the sheath 40. (Column 12, Line 63 through Column 13, Line 20) Sullivan also discloses that a force is imposed on said stent pusher 30A, transferring said force to the stent graft 34 to move said stent graft relative to the sheath 40, thereby deploying said stent graft 34.

Regarding claims 2, 7, 15, 16, 20, and 27, Sullivan discloses that the protrusions are helically arranged so that the stent pusher can be withdrawn from the lumen of the stent by unscrewing the stent pusher relative to the stent lumen. (See Abstract)

Regarding claims 4, 6, 12, and 18, the stent matrix comprises nitinol. (Column 5, Lines 44-48) Sullivan does not discuss the material used to form the covering layers of the stent graft. It would have been obvious to one of ordinary skill in the art at the time of the invention to have the covering layers comprise ePTFE or polytetrafluoroethylene since it was a known material used in the formation of covering layers of stent grafts.

Regarding claim 8, 17, and 22, Sullivan does not disclose that the sheath has a tapered distal tip. It would have been obvious to one of ordinary skill in the art to provide the sheath with a tapered distal tip in order to better retain the stent within said sheath. Said tapered distal tip would narrow to a size appropriate to receive a guidewire.

Regarding claim 9, Sullivan discloses that the inner catheter has a tapered distal tip positioned distal of the sheath. (Figure 7)

Regarding claims 13, 14, and 26, it was well known to provide markers on such delivery implements to allow a physician to accurately locate important elements. It would have been obvious to provide a plurality of markers arranged circumferentially about a proximal and distal end of the stent in order to allow a physician to accurately determine the location of the stent for delivery. It would have been obvious for said markers to comprise tantalum since tantalum was a material commonly used for fabrication of medical markers.

Regarding claim 15, 16, 27, Sullivan discloses that the protrusions 38 may be helically arranged around the outer surface of the pusher 30. Arranged helically, the protrusions comprise a wire bonded helically about an outer surface of the distal end of the stent pusher. (Figure 3A)

Regarding claims 16, 23, and 27, Sullivan does not disclose that the inner catheter and wire comprise stainless steel. It would have been obvious to one of ordinary skill in the art at the time of the invention to have said elements comprise stainless steel since it was a known material from which to form medical instruments designed to be inserted into the body.

Regarding claim 21, the pusher has an outside diameter smaller than a luminal diameter of the stent.

Regarding claim 24, the inner catheter defines a guidewire lumen. (Figure 3A)

Regarding claim 25, rapid exchange delivery systems wherein a guidewire lumen is only in a distal zone of the delivery system were well known at the time of the invention. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Sullivan by making the delivery system a rapid exchange system such that the guidewire lumen is only in a distal zone of the delivery system in order to allow the system to be quickly exchanged for a new catheter system without having to insert a new guidewire to the delivery site.

Regarding claims 28-30, Sullivan discloses withdrawing the outer sheath to deploy the stent at the stenting site. (Column 5, Lines 10-20) Said withdrawing step

includes moving the proximal end of the outer sheath in a proximal direction, such that a tip of the outer sheath stretches and slides over an abluminal wall surface of the stent.

Regarding claim 31, the outer sheath 40 of Sullivan runs along the length of the inner catheter 30A and, as such, is withdrawn as a unit from the proximal end. It would have been obvious to one of ordinary skill in the art to provide an outer sheath only over the distal end retaining stent 34 and using a pull wire to withdraw said modified outer sheath since these two methods of withdrawing a sheath are functional equivalents.

Regarding claim 32, the inner catheter is withdrawn from the lumen of the stent graft following the expansion thereof to an expanded diameter.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sullivan et al. (US 6,607,551) in view of Grosjean et al. (US 5,619,878).

Regarding claim 20, Sullivan teaches that the protrusions are helically arranged and that the stent graft is compressed onto said protrusions such that the luminal covering layer is deformed by said protrusions, but does not discuss withdrawing the stent pusher from the stent graft by unscrewing it. Grosjean teaches that it was well known to withdraw an inner element having a helical protrusion from a complimentary tubular element by unscrewing it. (Column 5, Lines 48-65) It would have been obvious to one of ordinary skill in the art at the time of the invention to withdraw the stent pusher from the stent graft by unscrewing it as taught by Grosjean.

Response to Arguments

Applicant's arguments filed July 1, 2008 have been fully considered but they are not persuasive.

Applicant argues that Sullivan discloses that the protrusions of the stabilizer contact members of the stent framework and fails to disclose that the protrusions deform a covering material or layer, as recited in Applicant's claims. Examiner acknowledges that Sullivan discusses at various points throughout the detailed description that the protrusions may directly engage portions of the stent framework. Examiner submits that it appears that the disclosure of Sullivan is primarily concerned with combining the delivery system an uncovered stent. This submission seems to be supported by the observation that none of the figures depict a covering on the stent. Since a luminal covering would clearly obstruct access to the stent's framework, it seems that the passages Applicant has cited wherein Sullivan discusses the protrusions directly engaging the framework of a stent are directed only to a first embodiment of the invention of Sullivan wherein the stent does not comprise a covering material.

Sullivan discloses an embodiment wherein the stent comprises a covering material disposed on both the inside and outside of the stent. (Column 1, Lines 18-27) Combining the retention system of Figure 3A with a stent having a covering layer disposed within the stent lumen, the protrusions would engage the inner covering layer rather than with the stent framework. In order for the protrusions to directly engage the stent framework, the protrusions would have to be sized and shaped to extend entirely through the inner covering layer, and the stent would have to be crimped down with

enough force for the protrusions to do so. Sullivan teaches that a mere frictional engagement between the protrusions and the stent is within the scope of the disclosure. Since such a frictional engagement would be achieved without forcing the protrusions entirely through the inner covering layer, it would have been obvious to one of ordinary skill in the art to crimp the covered stent of Sullivan onto the stabilizer with sufficient force to create a frictional engagement therebetween without extending the protrusions entirely through the inner covering layer in order to prevent damage to the stent.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric Blatt whose telephone number is (571)272-9735. The examiner can normally be reached on Monday-Friday, 9:00 AM-6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kevin T. Truong/
Primary Examiner, Art Unit 3734

Eric Blatt
571-272-9735